REMARKS

Applicant would like to thank Examiner Wong for the courteous and helpful discussion held with Applicant's representative on May 29, 2003. During the discussion, it was noted that candy manufacturers and other food industry professionals have long been aware of a very serious problem that diarrhea and associated gastrointestinal maladies may be caused by the consumption of polyol-containing foodstuffs. It was further noted that in spite of this long-standing awareness, there has hitherto been consistent failure within the industry to identify an adequate solution for preventing such severely undesirable side effects from afflicting the consumers of polyol-containing foodstuffs. In short, the link between gastrointestinal maladies such as diarrhea and the consumption of polyols represents a long felt but unsolved need within the food industry.

It was further noted during the discussion that the claimed invention provides a solution to the above-described long felt but unsolved need and that the efficacy of this solution requires that inulin be consumed in combination with sweetening agent in a particular minimum amount. This minimum amount, which corresponds to about 25 percent by weight of the combination of sweetening agent and inulin, is recited in each of independent claims 1, 13, 20, 21, 22, 26, and 28. This minimum amount of inulin represents a hitherto unrecognized solution to the long felt but unsolved need for preventing or minimizing diarrhea and/or related symptoms induced by the consumption of polyols. This minimum amount is not arbitrary nor is it a matter of mere optimization, as was previously suggested in the outstanding Office Action (e.g., page 3).

Claim Rejections – 35 U.S.C. § 103 (a)

The rejection of claims 1-29 under 35 U.S.C. § 103(a) as being unpatentable over Willibald-Ettle et al. (United States Patent No. 6,248,386), James (United States Patent No. 5,721,004), Teeuwen et al. (abstract), Thon (abstract), and Birch et al. (abstract) in view of Laurenzo et al. (European Patent Application No. EP 0 787 745 A2) is respectfully traversed. None of the applied references, alone or in combination, teaches or suggests the recited minimum amounts of inulin. Moreover, these minimum

amounts are not obvious inasmuch as the use thereof provid s a solution to a long felt but unsolv d need.

As noted during the discussion, Applicant respectfully submits that the *prima facie* case of obviousness has been overcome through the provision of ample rebuttal evidence establishing a long felt but unsolved need in the art; this rebuttal evidence includes the Exhibits submitted with the Response filed July 24, 2001 and new Exhibits submitted with the present Response. As noted in MPEP 2141.01, "[o]bjective evidence or secondary considerations such as ... long-felt need ... are relevant to the issue of obviousness and must be considered in every case in which they are present." As further noted in MPEP 2144.08(II)(B), rebuttal evidence for overcoming a *prima facie* case of obviousness "may include evidence of 'secondary considerations,' such as ... long felt but unsolved needs ... *Graham v. John Deere Co.*, 383 U.S. at 17, 148 USPQ at 467."

Evidence of Long Felt But Unsolved Need

As evidence of the long felt but unsolved need asserted by Applicant, Applicant has previously submitted Exhibits A, B, and C with the Response filed July 24, 2001. Exhibits A, B, and C are now resubmitted with the present Response for the convenience of the Examiner, although they have been re-labeled as Exhibits I, II, and III, respectively, for consistency with the labeling of the new Exhibits described below. Exhibit I shows a candy wrapper warning that the presence of the polyol ingredients lactitol and maltitol may produce a laxative effect. Exhibit II shows a candy wrapper warning that the presence of the polyol ingredients sorbitol or mannitol, or the presence of hydrogenated starch hydrolysate, may produce a laxative effect. Exhibit III shows candy wrappers from two foodstuffs produced by the same manufacturer, one of which contains a warning against the possibility of a laxative effect, the other of which does not. The foodstuff bearing the warning contains the polyol sucrose replacement maltitol, whereas the foodstuff without a warning contains ordinary sugar (i.e., sucrose).

As further evidence of the long felt but unsolved need asserted by Applicant, Applicant submits new Exhibit IV. Exhibit IV shows the label of a sorbitol solution, which identifies this polyol as having dual use as a sweetening agent and as a laxative.

As still further evidence of the long felt but unsolved need asserted by Applicant, Applicant submits new Exhibits V, VI, and VII, which are abstracts of papers drawn from the scientific literature. Exhibit V is an abstract of an article entitled "Dose-Related Gastrointestinal Response to the Ingestion of Either Isomalt, Lactitol or Maltitol in Milk Chocolate" by G. A. Koutsou et al. (*Eur. J. Clin. Nutr.* **1996**, *50*, 17-21), which describes that healthy volunteers aged 18-24 years who ingested polyol-containing milk chocolate experienced gastrointestinal responses including flatulence, borborygms, colic, increased motion frequency, and loose stools. Exhibit VI is an abstract of an article entitled "Sugar Alcohols as Bulk Sweeteners" by W. L. Dills, Jr. (*Annu. Rev. Nutr.* **1989**, *9*, 161-186), which states that "[a]ll of the polyols can cause osmotic diarrhea in humans if higher levels are consumed," and that "[t]his fact is noted in the labeling of products containing mannitol and sorbitol in the United States." Exhibit VII is an abstract of an article entitled "Use of Xylitol as Sugar Substitute in Diabetic Children" by H. Forster et al. (*Fortschr. Med.* **1977**, *95*, 99-102), which indicates that a diabetic child given xylitol as a substitute for sugar was unable to continue in the study due to the onset of diarrhea.

It is abundantly clear from a consideration of Exhibits I, II, and III that the manufacturers of the foodstuffs originally packaged in these wrappers were well aware of the serious problems associated with the ingestion of polyols. Furthermore, it is abundantly clear from a consideration of Exhibit IV that a foodstuff manufacturer wishing to employ sorbitol as a sweetening agent would be well aware of the possible undesirable laxative effect that could result from ingestion thereof. Moreover, it is abundantly clear from a consideration of Exhibits V, VI, and VII that the cause-effect relationship between polyol-consumption and diarrhea and/or related symptoms is very well established and recognized within the art. Nonetheless, in spite of the widespread recognition of the link between polyol-consumption and gastrointestinal disorders, manufacturers and providers of polyol-containing foodstuffs have been wholly incapable of mitigating or preventing the undesirable effects of polyol consumption beyond providing generic warnings discouraging excessive consumption, such as those illustrated in Exhibits I, II, III, and IV.

This long felt but unsolved need, evidenced by the Exhibits described above, is successfully addressed by use of the claimed invention, in which inulin is added to sweetening compositions in the claimed amounts (e.g., specification, page 7, lines 3-7). However, none of the cited references, alone or in combination, teaches or suggests inulin in an amount which comprises at least about 25 percent by weight of a combination of sweetening agent or agents and inulin—that is, in an amount sufficient to reduce diarrhea induced by sweetener consumption. Indeed, none of the cited references even acknowledges or recognizes that diarrhea induced by sweetener consumption may be reduced or eliminated through the use of inulin.

Applicant respectfully submits that if the claimed invention would have been obvious in view of the cited references, which Applicant respectfully submits that it would not have been, then manufacturers of polyol-containing foodstuffs would have long ago employed Applicant's invention in order to reduce the undesirable side effects associate with consumption of their products, thus boosting sales, increasing consumer satisfaction, etc. The fact that the claimed invention has not previously been recognized as a viable solution to the long felt but unsolved need is a testament to the non-obviousness of the claimed invention.

In accordance with the mandates of MPEP 2141.01 quoted above, Applicant respectfully submits that the *prima facie* case of obviousness has been overcome in view of the above-described rebuttal evidence. For at least the reasons set forth above, Applicant respectfully submits that the claimed invention is neither anticipated by nor would have been obvious in view of the cited references, alone or in combination. Accordingly, withdrawal of this ground of rejection is respectfully requested.

Conclusion

In view of the Remarks set forth above, Applicant respectfully submits that the claimed invention is in condition for allowance. Early notification to such effect is earnestly solicited.

If for any reason the Examiner feels that the above Remarks do not put the claims in condition to be allowed, and that a discussion would be helpful, it is

respectfully requested that the Examiner contact the undersigned agent directly at (312)-321-4257.

Respectfully submitted,

Gregory Zayla
Registration No. 48,059
Agent for Applicant

BRINKS HOFER GILSON & LIONE
P.O. BOX 10395
CHICAGO, ILLINOIS 60610
(312) 321-4200

VERSION WITH MARKINGS TO SHOW CHANGES MADE

Amendments to claim 23:

23. (Once Amended) A foodstuff comprising a sweetening composition as recited in any one of claims 1, 13, 14, 20, 21[,] or 22 [or 23].

Amendments to claim 24:

24. (Once Amended) A foodstuff comprising a sweetening composition as recited in any one of claims 1, 13, 14, 20, 21[,] or 22 [or 23], wherein said foodstuff is selected from the group consisting of gum, candy, ice cream, cheese, yogurt, cottage cheese, cake, cookies and beverages.

EXHIBIT I

The Fannie May Legacy

Quality isn't just a word at Fannie May, it's a way of life... and has been for over 75 years. By using only the freshest ingredients, Fannie May continues to make the finest candies available... as good as the day H. Teller Archibald opened his first Fannie May Shop in 1920 in Chicago, Illinois.

Our commitment to freshness continues and you will taste the difference. We guarantee it.

Enjoy the quality of Fannie May Candies with these sugar free fruit-flavored pops in an assortment of grape, lemon, lime, orange, cherry, and pineapple. Fannie May Candies... quite simply the finest candies available.

Sugar free candies are made for those who prefer less sugar or are on a sugar-restricted diet. Although this is not a reduced calorie product, it will not promote tooth decay. This product may produce a laxative effect after excessive consumption. People on a restricted diet should consult their physician before consuming.

Ingredients: Lactitol, Maltitol Syrup, Aspartame, Citric Acid, Natural and Artificial Flavor, Yellow #5, Yellow #6, Red #40, Red #3, Blue #1

Phenylketonurics: Contains Phenylalanine

Manufactured by Fannie May Candies, a division of Archibald Candy Corporation Chicago, IL 60607

Nutrition Facts

Serving Size 1 piece (10.5 g)
Servings per Container 12

Amount Per Serving		
Calories 42	Calories from Fat 0	
		% Daily Value*
Total Fat 0g		0%
Saturated Fat 0g		0%
Cholesterol 0mg		0%
Sodium 0mg		0%
Total Carbohydrates 10g		3%
Dietary Fiber 0g		
Sugars 0g		
Protein 0g		

Vitamin A 0% • Vitamin C 0%
Calcium 0% • Iron 0%

*Percent Daily Values are based on a 2,000 calorie diet. Your daily values may be higher or lower depending on your calorie needs.

	Calories	2000	2500
Total Fat	Less than	65g	80g
Sat. Fat	Less than	20g	25g
Cholesterol	Less than	300mg	300mg
Sodium	Less than	2400mg	2400mg
Total Carbohydrate		300g	375g
Dietary Fiber		25g	30g

Calories per gram
Fat 9 · Carbohydrates 4 · Protein 4

EXHIBIT II

"One Taste ... Our Best Advertisement!"®

EDA Candies are manufactured with sorbitol, a cool refreshing sugar substitute which occurs naturally in many fruits and berries. Sorbitol has been thoroughly tested and widely used for over 100 years. EDA candies are made without artificial sweeteners and contain no saccharin, acesulfame potassium or aspartame.

Dry Mouth?, Get your juices flowing with delicious EDA candies!
"Melts in your mouth not in the wrapper!"

Nutrition Facts

Serving Size 5 pieces (15g)
Servings Per Container about 11

Amount Per Serving	
Calories 60	
	% Daily Value*
Total Fat 0g	0%
Cholesterol 0mg	0%
Sodium 0mg	0%
Total Carbohydrate 15g	5%
Sugars 0g	
Sorbitol 15g	
Protein 0g	

Not a significant source of Calories from Total Fat, Saturated fat, Dietary Fiber, Vitamin A, Vitamin C, Calcium, and Iron.

* Percent Daily Values are based on a 2,000 calorie diet.

Available in 21 mouth water flavors....

MIXED FRUITS	TROPICAL MIX	OLD-TYME MIX
Cherry	Banana	Butterscotch
Green Apple	Butter Rum	Chocolate
Lemon	Coconut	Cinnamon
Lemon-Lime	Lemon-Lime	Icy Peppermint
Orange	Orange	Licorice
Raspberry	Pina Colada	Real Coffee
Strawberry	Pineapple	Root Beer
Watermelon	Watermelon	Spearmint

Ingredients:
Sorbitol, gum arabic, citric acid, natural and artificial flavors, colors added. (FD&C Red # 40, Blue #1, Blue #2, Turmeric)

EXCHANGE INFO: 1 serving=1fruit exchange. Those exchanges are useful for people with diabetes and those in weight loss programs.

DIABETICS: This product may be useful in your diet on the advice of a physician. This is not a reduced calorie food.

As in all candies made with sorbitol, mannitol, or hydrogenated starch hydrolysate, EXCESSIVE CONSUMPTION MAY HAVE A LAXATIVE EFFECT IN SENSITIVE PERSONS. According to the FDA, 50 grams (17 candies- about 3 servings) is well tolerated by most individuals. Since sensitivity varies among individuals, we recommend starting with one or two candies and gradually increasing as desired. A tolerance can be developed in much the same way as with fiber.

Questions or comments about this product?
Call toll-free weekdays: (9-3 EST) 1-800-438-3327

Manufactured by
LEHMAN SUGAR FREE CONFECTIONS, INC.
BROOKLYN, NY 11203 (800-GET-EDAS)

BEST AVAILABLE COPY

EXHIBIT III

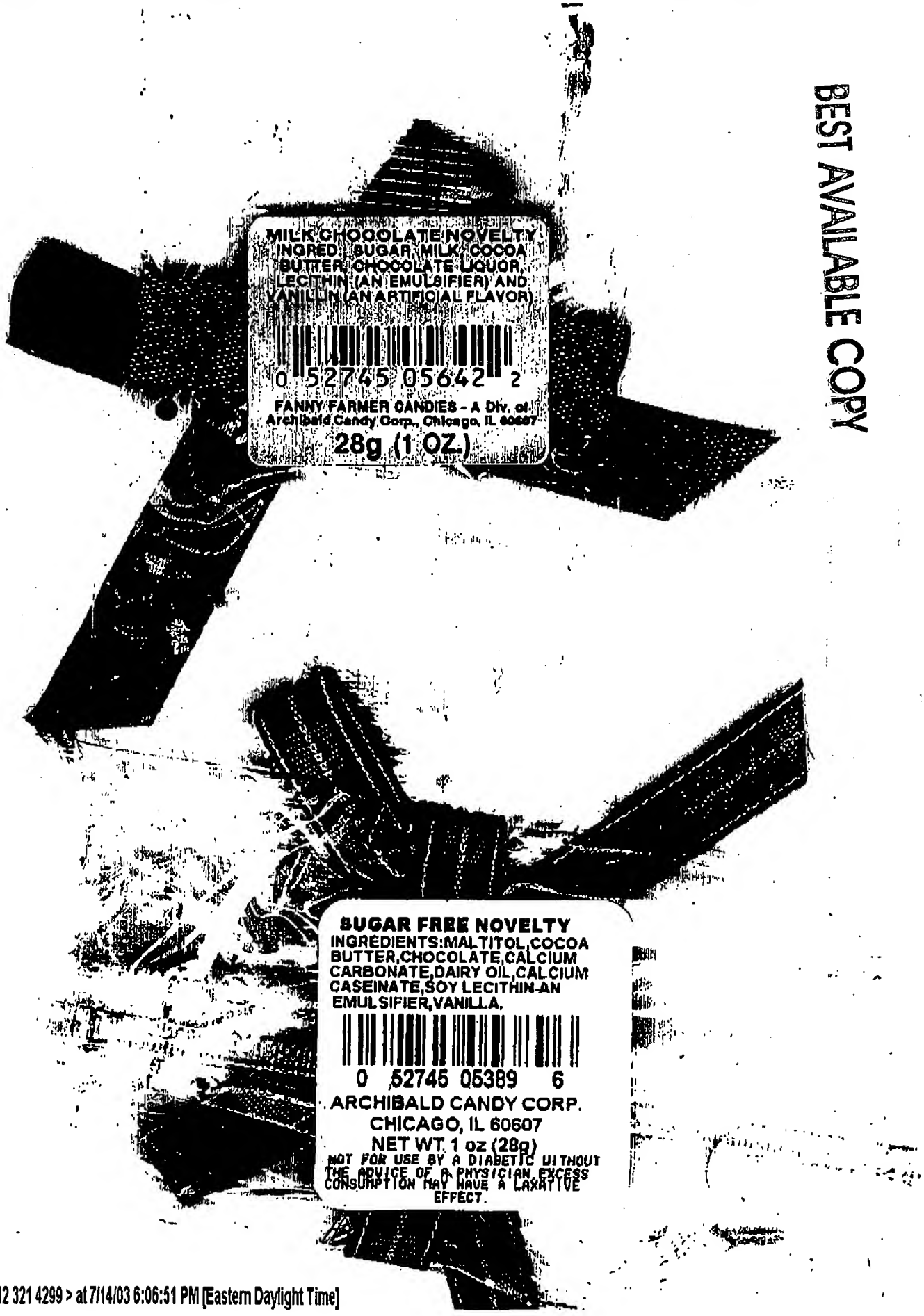

EXHIBIT IV

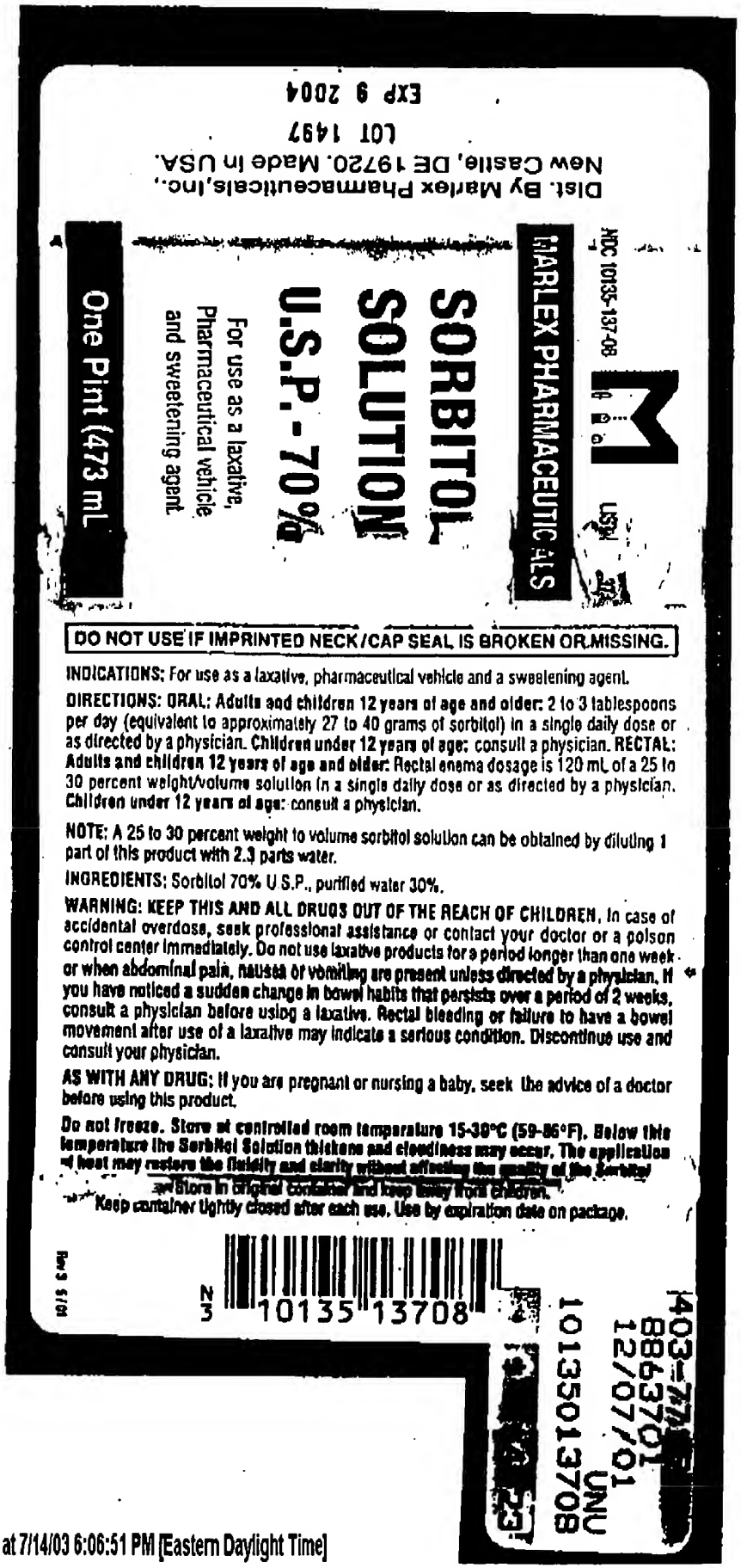

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EXHIBIT V

Eur J Clin Nutr. 1996 Jan;50(1):17-21.

Related Articles, Links

Dose-related gastrointestinal resp nse to the ingestion of either isomalt, lactitol or maltitol in milk chocolate.

Koutsou GA, Storey DM, Lee A, Zumbe A, Flourie B, leBot Y, Olivier P.

Nutritional Biosciences Unit, University of Salford, UK.

OBJECTIVES: To determine whether there were differences between different polyols (sugar alcohols) in terms of their ability to stimulate intolerance symptoms when consumed in milk chocolate. Also to discover whether symptomatology can be related to the dose of polyol ingested. DESIGN: The study was of a randomised double-blind cross-over design. SUBJECTS: 59 healthy volunteers aged 18-24 years were recruited from the student population of the University of Salford. All subjects successfully completed the trial. INTERVENTIONS: Subjects ingested 100 g milk chocolate containing 40 g bulk sweetner as either sucrose, isomalt, lactitol or maltitol or a mixture (10:30 w/w) of sucrose and isomalt, sucrose and lactitol or sucrose and maltitol. Each bar was taken as breakfast on one day with following products consumed at 1-week intervals. Subjects reported the incidence and severity of the symptoms of flatulence, borborygms, colic, motion frequency and loose stools. RESULTS: The ingestion of 30 g or 40 g lactitol resulted in a significant increase in the incidence and severity of all symptoms examined compared to reactions after the consumption of standard sucrose-containing chocolate ($P < 0.01$). Similarly, 40 g isomalt led to an increased incidence of all symptoms, including mild laxation ($P < 0.01$), but unlike lactitol none was rated as being severe. A reduction in isomalt to 30 g was marked by increased tolerance with evidence of only mild borborygms ($P < 0.01$), mild flatulence, colic, and laxation ($P < 0.05$), with no increase in motion frequency ($P < 0.35$). Ingestion of 40 g maltitol caused less intolerance than 40 g isomalt, with evidence of only flatulence, borborygms and colic ($P < 0.01$), symptoms being rated as only mild. A reduction to 30 g led to a decrease in all symptoms except mild flatulence. Maltitol did not have any laxative effect when ingested at either 30 g ($P = 0.32$) or 40 g ($P = 0.13$) per day. CONCLUSIONS: This work has shown that there are significant differences in the reporting of gastrointestinal symptomatology following the consumption of isomalt, lactitol and maltitol incorporated into milk chocolate. However, with all three polyols the incidence and severity of symptomatology was dose dependent.

Publication Types:
- Clinical Trial
- Randomized Controlled Trial

PMID: 8617186 [PubMed - indexed for MEDLINE]

EXHIBIT VI

Annu Rev Nutr. 1989;9:161-86.

Related Articles, Links

Sugar alcohols as bulk sweeteners.

Dills WL Jr.

Department of Chemistry, Southeastern Massachusetts University, North Dartmouth 02747.

The polyols are a family of bulk sweeteners, some of which are currently used in the United States and in other nations. The use of these compounds is likely to increase in the future. The greatest advantage of polyols as sweeteners is their reduced cariogenicity compared with sucrose, fructose, or glucose. This reduced cariogenicity has been observed with all of the polyols considered in this review. Furthermore, evidence suggests that one of these polyols, xylitol, may have cariostatic properties. More research is needed to clarify the mechanism of this cariostatic effect. Evidence suggests that moderate usage of the polyols in human diets over long periods is not likely to produce many toxic effects. This conclusion is supported by the facts that (a) both sorbitol and mannitol have been used as sweeteners for some time without apparent side effects, and (b) extensive long-term studies with dietary xylitol in Europe have not yielded any reports of toxicity. At this point there is no reason to believe that the disaccharide polyols differ significantly in a qualitative sense from sorbitol or mannitol with regard to their effects in humans. There are some research needs with regard to the inclusion of the polyol sweeteners in human diets: 1. All of the polyols can cause osmotic diarrhea in humans if higher levels are consumed. This fact is noted in the labelling of products containing mannitol and sorbitol in the United States (see "Current Regulatory Status"). If the disaccharide polyols are to be used as bulk sweeteners, further studies of the dose levels that can cause diarrhea may be needed. 2. The polyols, like other slowly absorbed carbohydrates, enhance the absorption of certain minerals, particularly divalent cations. More comparative and mechanistic studies of this effect are needed. 3. All of the polyols, lactose, and other slowly absorbed carbohydrates appear to cause adrenal medullary hyperplasia at high doses in laboratory rats. Evidence suggests that these lesions are linked in some way to the lactose or polyol-induced changes in calcium homeostasis. Despite long-term use of lactose, sorbitol, and mannitol in human diets, similar lesions in humans have not been reported and some investigators have concluded that the lesion in rats has no relevance to humans. Nevertheless further studies are needed to elucidate the mechanisms of the dietary lactose and polyol-induced adrenal hyperplasias in rats to ascertain definitively if they also operate in other species.(ABSTRACT TRUNCATED AT 400 WORDS)

Publication Types:
- Review
- Review Literature

PMID: 2669868 [PubMed - indexed for MEDLINE]

EXHIBIT VII

Fortschr Med. 1977 Jan 13;95(2):99-102.

Related Articles, Links

[Use of xylitol as sugar substitute in diabetic children]

[Article in German]

Forster H, Boecker S, Walther A.

In 24 diabetic children treated with insulin xylitol was used as a sugar substitute for four weeks in an amount of 30 gms/day. In one case only the xylitol application was terminated before the end of the dietetic period because of diarrhoea. The other children tolerated xylitol fairly well, three of the children found the polyol too sweet. Because of incomplete data, the values of only 18 children were compiled. A significant increase of serum uric acid concentration measuring 1 mg/100 ml was the main side effect of xylitol usage. This effect was favoured by the fact that diabetic children do not use sucrose. As was shown earlier, a sucrose free period is the precondition for the possibility to find a xylitol induced hyperuricemia. In metabolically healthy children the existence of a sucrose induced hyperuricemia is also to be expected, this xylitol effect is, therefore, obviously without pathophysiological significance. Xylitol is suited for use as a sugar substitute in diabetic diet and in caries prophylaxis if the limited dose is observed.

PMID: 832837 [PubMed - indexed for MEDLINE]